

REMARKS

Claims 15-29, 31 and 32 are presently in the application. Claims 1-14 and 30 have been canceled.

Claims 15-32 have been rejected under 35 USC 112, second paragraph, as indefinite. Claims 15-29, 31 and 32 have been amended to overcome the rejection, taking into account the examiner's comments. Claim 30 has been canceled. It is respectfully submitted that the claims are now in full compliance with the requirements of 35 U.S.C. 112, second paragraph.

Claims 15-20 and 29 have been rejected under 35 USC 102(b) as anticipated by Fraser et al (US 3,851,436).

Claim 15 is directed to a method for sterilizing vessels, comprising exciting a plasma in an interior region and at an exterior region of a vessel by electromagnetic oscillations, wherein the plasma sterilization in the interior region of the vessel and at the exterior region of the vessel are performed at different times by selective excitation of the plasma, the selective excitation of the plasma being effected by separate control of the pressure inside and outside the vessel (2), with the result that the plasma sterilization is performed in various regions of the walls of the vessel (2) in which plasma excitation takes place as a result of a pressure sufficiently below atmospheric pressure.

In the exemplary embodiments of the invention shown in Figs. 1 and 2, a selective excitation of the plasma takes place. By means of different gas pressures in the interior of the vessel 2 and in the surrounding chamber 3 that are engendered at least intermittently during the method steps, the plasma can be purposefully excited either on the inside or the outside of the vessel. If the pressure in either the vessel or the chamber is too low, not enough elementary

particles can be excited or ionized to maintain a plasma discharge. If the gas pressure is too high, the mean free travel length is too short to allow the elementary particles enough acceleration distance or acceleration time between two pulses for activation or excitation and thus for ionization. In other words, the plasma can be effected inside or outside the vessel by separate control of the gas pressure inside and outside the vessel.

In the first exemplary embodiment of Fig. 1, the chamber 3 is pumped out using the pump 9 in such a way that the gas pressure in its interior of the chamber 3 is too low to excite a plasma. In the chamber 3, the vessels 2 to be sterilized are held in such a way that they are seated by positive engagement directly with their opening on a cone 4. Via a feed line 7, a defined gas flow, for instance comprising oxygen, filtered air, steam, hydrogen peroxide vapor, argon, nitrogen, tetrafluoromethane, sulfur hexafluoride or the like, flows from outside the chamber, controlled by the throughput regulator 6, through the interior of the cone 4 into the vessel 2. This gas flow is set such that in the interior of the vessel 2, the pressure becomes so high that a plasma can be excited in the interior of the vessel.

To obtain a desired pressure or at a defined pressure to obtain a defined gas exchange in the vessel 2 of Fig. 1, the gas, or the waste gas from the plasma, is evacuated by suction from the vessel 2 into the chamber 3 via the groove 5 on the outside of the cone 4. As a function of the quantity of gas flowing in through the cone 4 and of the guide value of the groove 5, the pressure of the gas in the vessel 2 can be established. The leakage of gas from the interior of the vessel to the chamber via the groove can be control by a valve located in the groove or by suitable design of the groove cross section. The waste gas that has flowed into the chamber 3 through the groove

5 is then evacuated from the chamber 3 by suction by the pump 9 in order to maintain the pressure ratios, and as a result, a plasma is generated selectively only in the interior of the vessel 2 to be sterilized.

In an especially advantageous refined version of this selective sterilization process, the chamber 3 of Fig. 1 is first pumped out completely, without allowing a gas flow into the vessel 2 or into the chamber 3. Next, the throughput regulator 6 is opened to generate a defined gas flow, which flows into the vessel 2 to be sterilized and in the interior of the vessel 2 ignites a plasma, advantageously by means of microwave emission from the plasma source 8.

Once the desired sterilization effect in the interior of the vessel 2 is reached, it is optionally also possible in the chamber 3, that is, outside the vessel 2 to be sterilized, to raise the gas pressure by having a defined flow of the same gas or gas mixture that flows through the feed line 7, or optionally through an additional feed as well, not shown here, to be let into the chamber 3, so that a plasma can be excited here as well. The plasma is extinguished in the interior of the vessel 2 then and is excited outside, in the chamber 3. With this method step, the vessel 2 can thus also be sterilized on the outer wall, oriented toward the chamber 3.

This process of the outward propagation of the plasma formation occurs because a plasma shields itself off from the outside, that is, absorbs the energy emitted into it, to such an extent that the energy outside this plasma is not sufficient to excite a further plasma. Thus the outer plasma in the chamber 3 is shielded from the partitioned-off gas atmosphere in the interior of the vessel 2 to be sterilized and prevents the excitation of a plasma there. If the pressure in the chamber 3 is too low, but if the pressure in the interior of the vessel is adequate for a plasma, then the energy emitted into it is largely absorbed in the inner plasma of the vessel 2. However, in the other case,

since the energy of the plasma source 8 is first emitted into the chamber 3, and only then (possibly damped by the wall of the vessel 2 to be sterilized) does it reach the interior of the vessel 2, the plasma is created immediately on the outside of the vessel 2, as soon as the gas pressure for this purpose is adequate in the chamber 3.

At col. 3, ll. 28-30, Fraser teaches that "the gas plasma flows through the interior of the oxygenator 2' and then over the exterior of the oxygenator sequentially." This could be interpreted as meaning that the excitation of a plasma in the interior region of the vessel (oxygenator) is performed before the excitation of a plasma in the exterior region of the vessel (oxygenator). However, Fraser does not teach or suggest that plasma sterilization in the interior region of the vessel and at the exterior region of the vessel are performed at different times by selective excitation of the plasma, the selective excitation of the plasma being effected by separate control of the pressure inside and outside the vessel (2), with the result that the plasma sterilization is performed in various regions of the walls of the vessel (2) in which plasma excitation takes place as a result of a pressure sufficiently below atmospheric pressure.

In Fraser, the pressure is not controlled with a view to a plasma generation. The plasma generation is effected solely by means of the RF oscillator 7. The pressure in Fraser controls only the quantity of the plasma gas that flows through the sterilization chamber (col. 1, ll. 54-58). On the other hand, Fraser discloses that the surface should be exposed to a certain low atmospheric pressure, to improve the sterilization (col. 3, ll. 44-48). However, controlling the excitation of the plasma by controlling the pressure in the interior of the vessel and at the exterior of the vessel

to either excite a plasma in either the interior of the vessel or at the exterior wall of the vessel is neither disclosed nor made obvious by Fraser.

To support a rejection of a claim under 35 U.S.C. 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

Fraser does not teach a method for sterilizing vessels of the type recited in claim 15 in which plasma sterilization in the interior region of a vessel to be sterilized and at the exterior region of the vessel are performed at different times by selective excitation of the plasma, the selective excitation of the plasma being effected by separate control of the pressure inside and outside the vessel, with the result that the plasma sterilization is performed in various regions of the walls of the vessel in which plasma excitation takes place as a result of a pressure sufficiently below atmospheric pressure. Accordingly, claim 15 and claims 16-20 and 29 are not anticipated by Fraser.

Claims 21-23 and 31 have been rejected under 35 USC 103(a) as unpatentable over Fraser et al.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Fraser does not teach a method for sterilizing vessels of the type recited in claim 15 in which plasma sterilization in the interior region of a vessel to be sterilized and at the exterior region of the vessel are performed at different times by selective excitation of the plasma, the

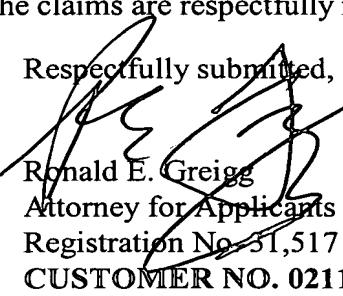
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selective excitation of the plasma being effected by separate control of the pressure inside and outside the vessel, with the result that the plasma sterilization is performed in various regions of the walls of the vessel in which plasma excitation takes place as a result of a pressure sufficiently below atmospheric pressure. Accordingly, claim 21-23 and 31 are not rendered obvious by the teachings of Fraser.

Claims 24, 25, 27 and 28 have been rejected under 35 USC 103(a) as unpatentable over Fraser et al in view of Hoeck (US 4,544,529) or Schultze (US 2,501,193) and claim 26 has been rejected under 35 USC 103(a) as unpatentable over Fraser et al in view of Hoeck or Schultze in combination with Schroeder et al (US 6,328,928 or WO 98/30491).

None of Hoeck, Schultze or Schroeder et al teaches that which is missing in Fraser, as set forth above. Therefore, even if the teachings in Fraser were combined with those in Hoeck, Schultze and/or Schroeder, one of ordinary skill in the art would not have arrived at applicants' invention.

Entry of the amendment and allowance of the claims are respectfully requested.

Respectfully submitted,

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